DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93904d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

Via FEDEX

March 7, 2003

Steven Heuer
Cocoon Nutrition
990 West Fremont Avenue
Suite K
Sunnyvale, CA 94087

Dear Mr. Heuer,

This letter concerns Cocoon GH-Liquid Spray Growth-600 ng [somatotropin], also known as recombinant human growth hormone.

Your Internet site www.cocoonnutrition.org from which you can order this product, includes claims such as "very powerful Anti-aging benefits of injectable GH... is now available in an orally-absorbable form-without a prescription and at a fraction of the cost ...rejuvenation of the skin and bones and regeneration of the heart, liver, lungs, and kidneys, bringing back organ and tissue function to more youthful levels. GH revitalizes the immune system, lowers the risk factors of heart attack and stroke improves oxygen uptake, and helps prevent osteoporosis. It is a powerful anti-obesity hormone and acts to naturally enhance sexual function. For many it acts like a natural cosmetic, restoring skin elasticity, smoothing wrinkles, and rejuvenating hair and nails... Cocoon GH is actual Growth Hormone. It rebuilds cells, regenerates organs, and has many long term benefits.. it can regenerate the size and function of the adrenal glands, sex organs, brain, liver, and all the other glands and tissues of the body." Testimonials included on your web site also convey the intended drug status of your product. Examples of these claims include but are not limited to; the improvement or cure of osteoarthritis, back injury, kidney failure, repetitive stress injury, tendonitis, serious hip joint pain, irregular heart beat and diabetic blood sugar levels.

On your Internet site, you state "GH is now available in an orally-absorbable form – without a prescription and at a fraction of the cost!" In the Directions For Use section of your web page, it states that the product sprayed "directly onto the inner cheek and hold for 90 seconds..." Cocoon GH is intended to bypass the alimentary canal by direct

absorption through the oral mucosa, and is therefore not a dietary supplement because it is not intended for ingestion. 21 U.S.C. 321(ff)(2)(A)(I) defines the term, "dietary supplement" to mean a product that is "intended for ingestion." Consequently, a product that is not intended for ingestion for ingestion cannot be a "dietary supplement."

Further, "growth hormone" was not marketed as a dietary supplement, or as food prior to its approval as a drug. Therefore, growth hormone is excluded from the definition of a dietary supplement under 21 U.S.C. 321(ff)(3)(B) because growth hormone is an article approved as a new drug under 21 U.S.C.355.

Based on the claims made for this product, Cocoon GH is a "drug" as defined in 21 U.S.C. 321(g). Moreover, Cocoon GH" is a "new drug" as defined in 21 U.S.C. 321(p) because this product is not generally recognized as safe and effective for its intended uses. Since this product is a new drug, it may not be marketed in the United States Food without an approved new drug application (NDA) [21 U.S.C. 355(a)]. In addition, Cocoon GH is misbranded under 21 U.S.C. 352(f)(1) because its labeling fails to bear adequate directions for the uses for which it is offered.

Since you promote and distribute the Cocoon GH product for health related claims that are not the subject of an FDA approved NDA, you are also in violation of 21 U.S.C. 333(e). This section states that "...whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under 21 U.S.C. 355 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title18, United States Code, or both."

This letter is not intended to be an all-inclusive review of your Internet sites, and the products your firms may market. The violations of the Act described above are not intended to be all-inclusive list of the deficiencies of you and your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with Federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they make take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure, injunction, or criminal prosecution pursuant to 21 U.S.C. 333(e).

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action your firm will take to discontinue marketing of this drug product. Your response should be directed to Russell A. Campbell, Compliance Officer, at the U.S. Food and Drug Administration, San Francisco District, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley,
Director
San Francisco District Office

cc:

Patricia Harris, Executive Officer
California Board of Pharmacy
400 R Street, ste. 4070
Sacramento, CA 95814